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CENTRAL FAX CENTERSerial No. 09/938,937  
Art Unit: 1634

NOV 20 2006

**REMARKS**

This is a full and timely response to the outstanding final Office Action mailed July 19, 2006. Through this response, Declarations submitted under 37 C.F.R. 1.132 are submitted. Reconsideration and allowance of the application and pending claims are respectfully requested.

**Response To Claim Rejections Under 35 U.S.C. §112, First Paragraph**

Claims 10-14 remain rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. In particular, the Examiner states that "[t]he claim(s) contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." *Office Action* at 2. Applicants respectfully traverse this rejection.

In *Glaser v. Strickland*, 220 USPQ 446 (Bd. Pat. Int. 1983) the Board stated the following as a general proposition: "Opinion testimony which purports to state that a particular feature or limitation of a claim or count is disclosed in an application involved in an interference and which explains the underlying factual basis for the opinion may be helpful and can be admitted."

Similarly, in the instant case, the declarations of the inventors submitted under 37 C.F.R. 1.132 state that the feature of a "universal array" in the pending application would be readily understood by one of skill in the art at the time of the filing of the instant application, and explain the underlying factual basis for why the claim term would be understood.

In addition, facts supporting expert opinion that an application meets the requirements of 35 U.S.C. 112 are entitled to some weight in as a basis for deciding that the specification complies with 35 U.S.C. 112. *In re Chilowsky*, 306 F.2d 908, 134 USPQ 515 (CCPA 1962). For at least this

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reason, the rejection under 35 U.S.C. § 112, first and second paragraphs should be withdrawn, based on the facts set forth in the inventors' declarations submitted herewith.

With respect to the rejection that the claims are not enabled, claim 10 recites the following: "different sequences of the first plurality of nucleic acids can be differentiated by location" and "wherein the nucleotide sequence of each nucleic acid of the second plurality is known." (emphasis added). The claim is clearly enabled by the specification for the recited language. See, e.g., specification at pp. 21-23 regarding the discussion of the universally spatially addressable array. Because the specification teaches how different sequences of the first plurality can be differentiated by location, and because the sequence of each acid of the second plurality is known, when the nucleic acids of the second plurality have hybridized to a target with a signal, and also to a first plurality, the sequence of the target can be determined. Applicants submit that on its face, claim 10 is clearly enabled by the specification, as noted by the attached Declarations.

In addition, claim 10 recites "a method of assaying target nucleic acid molecules by tagging and sorting the target molecules with a universal array..." (emphasis added). In view of this language, it is respectfully asserted that claims 10-14 define the invention in the manner required by 35 U.S.C. § 112. As noted in the attached Declarations, one skilled in the art, at the time the patent application was filed, would understand the term "universal array" and the fundamental concepts of how a universal array functions. In the specification itself, Applicants state the following: "[a]n alternative array-based method of analyzing nucleic acids has been described by several groups (Brenner USP 5,604,097; Morris et al. EP 97302313), and uses a universal spatially addressable array." *Specification* at p. 21, lines 18-20 (emphasis added). Furthermore, a brief perusal of issued patents prior to the filing of the instant application reveals

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that universal arrays were known and described in the art already. This is a completely appropriate method to determine if the specification is enabling for claims in a patent application.

The Manual of Patent Examination Procedure (MPEP) states the following:

The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date. *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004) ("a patent document cannot enable technology that arises after the date of application").... *In re Budnick*, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976) (In general, if an applicant seeks to use a patent to prove the state of the art for the purpose of the enablement requirement, the patent must have an issue date earlier than the effective filing date of the application.).

MPEP §2164.05(a).

In the instant case, there are at least two patent references that discuss and describe what universal arrays are, and how they function with the use of a first plurality and a second plurality of nucleic acids in addition to the target molecules. For example, U.S. Patent No. 6,268,147 issued to Beattie *et al.* on July 31, 2001 discusses and illustrates universal arrays at *e.g.*, FIGS. 1, 14A, 14B, 15A, 15B, and col. 35, line 60 – col. 35, line 67. By way of additional example, U.S. Patent No. 6,083,763 issued to Balch on July 4, 2000 also discusses universal arrays throughout, *e.g.*, at FIG. 5a and correlating discussion. Therefore, as noted in the Declarations submitted herewith, one of ordinary skill in the art, upon reading the specification as of the date of the filing of the patent application, would have understood how one is to determine the nucleotide sequence of a target molecule using a universal array.

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Accordingly, Applicants respectfully request that the rejections to these claims be withdrawn.

Response To Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 10-14 remain rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. In particular, the Office Action states, "Claim 10 is indefinite with respect to what constitutes the metes and bounds of a 'universal array.'" *Office Action* at 6. Applicants respectfully traverse. The Declarations submitted herewith by those clearly of at least ordinary skill in the art demonstrate that one skilled in the art at the time the specification was filed would have understood what is meant by the term "universal array". The Declarations demonstrate the factual evidence that supports this contention (*see* discussion above regarding patents in existence at the time of the filing of the instant application that discuss and/or refer to a "universal array"). For at least these reasons, Applicants respectfully request that the rejection of claims 10-14 under 35 U.S.C. § 112, second paragraph be withdrawn.

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**CONCLUSION**

In light of the foregoing amendments and for at least the reasons set forth above, Applicants respectfully submit that all rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims 10-14 are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested.

Any other statements in the Office Action that are not explicitly addressed herein are not intended to be admitted. In addition, any and all findings of inherency are traversed as not having been shown to be necessarily present. Further, any and all findings of well-known art and official notice, or statements interpreted similarly, should not be considered well known for at least the specific and particular reason that the Office Action does not include specific factual findings predicated on sound technical and scientific reasoning to support such conclusions.

If, in the opinion of the Examiner, a telephone conference would expedite the examination of this matter, the Examiner is invited to call the undersigned agent at (770) 933-9500.

Respectfully submitted,



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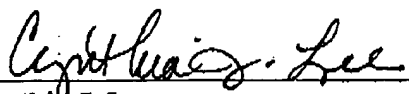
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